K121161
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510k Summary of Safety and Effectiveness
As required by Section 21 CFR 807.92©

JUL 13 2012

Acta Medical

Date Submitted:	March 26, 2012
Submitted By:	Acta Medical 15 Minneakoning Road, Suite 203 Flemington. NJ 08822 908-399-0279 Fax(908)-788-2788 Contact email: brewerjh@comcast.net
Submitter Contact:	John Brewer Acta Medical 4 Nevius Drive, Flemington, NJ 08822 brewerjh@comcast.net Tel:908-399-0279 Fax:908-788-2788
Common Name of Device:	Empty EVA Solution Container
Predicate Device:	EVA Empty Solution Container (K030888) Churchill Dual Chamber Empty Container (K041038)
Panel:	General Hospital and Personal Use
Product Code:	KPE
Device Classification:	IV Container, Class II, 21CFR880.5025
Manufacturing Location:	Yangzhou Wei De Li Trade Co. Ltd. Li Xin Bridge Touqiao Township. Yangzhou City, Jiangsu Province. China Tel: +86-514-87897887 Fax: +86-514-87889967

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Name & Model Numbers of Devices:

1. ACTINF250, Empty EVA Solution Container 250ml
2. ACTINF1000, Empty EVA Solution Container 1000ml
3. ACTINF2000, Empty EVA Solution Container 2000ml
4. ACTINF3000, Empty EVA Solution Container 3000ml
5. ACTINF750D, Empty EVA Dual Chamber Solution Container 750ml
6. ACTINF1500D, Empty EVA Dual Chamber Solution Container 1500ml
7. ACTINF3000D, Empty EVA Dual Chamber Solution Container 3000ml

Device Description:

Acta Medical Empty EVA Solution Container is designed to hold intravenous fluid in a single chamber or in dual chambers separated by a separating partition. Empty EVA Solution Container and Empty EVA Dual Chamber Solution Container has fill ports to fill single and dual chambers, latex free injection port for additions of injectable additives and a spike port to connect intravascular administration tubing. The fill port tubing has a sealing clamp to secure the contents during storage post filling and prior to their administration.

Device Intended Use: Empty EVA Solution Container

An Empty Container with sterile fluid pathway used to store intravenous solution for administration to patient. Medication transfer in and out of the container is done using aseptic technique.

Substantial Equivalence:

Acta Medical Empty EVA Solution Container is substantially equivalent to the predicate devices. Acta Medical Empty EVA Solution Container, device design, component materials, indication for use, SAL are substantially equivalent to the predicate devices.

Acta Medical EVA Mixing Container has been subjected to a variety of tests to demonstrate safety of the proposed device. These tests include biocompatibility, material strength, physical and chemical testing, leak testing and stability testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Aaron Compton
Acta Medical LLC
929 Arbor Downs SR
Plano, Texas 75023

JUL 13 2012

Re: K121161
Trade/Device Name: Empty EVA Solution Container
Regulation Number: 21 CFR 880.5025
Regulation Name: I.V. Container
Regulatory Class: II
Product Code: KPE
Dated: March 26, 2012
Received: April 17, 2012

Dear Mr. Compton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):_____

Device Name:___Empty EVA Solution Container

Indications For Use: An Empty Container with sterile fluid pathway used to store intravenous solution for administration to patient. Medication transfer in and out of the container is done using aseptic technique.

Prescription Use ___x____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

7/13/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121161